K002406

FEB 1 5 2001

510(k) Summary

Trade Name: **Mitek RapidLoc™ Meniscal Repair System**

Sponsor:
Mitek Products
249 Vanderbilt Avenue
Norwood, MA 02062
Registration #1221934

Contact:
Christine Kuntz-Nassif
Sr. Regulatory Affairs Associate
Telephone: (781) 251-2974
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Device Generic Name: Fastener Fixation, Biodegradable, Soft Tissue

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Product Code: 87 MAI

Predicate Devices: K970119 - Mitek "H" Fix; NDA#18-331 – PDS Absorbable Suture

Product Description: The Mitek RapidLoc™ Meniscal Repair System described in this 510(k) is a sterile, two piece implantable device consisting of a molded PLA Backstop and Tophat.

Indications for Use:
The RapidLoc™ Meniscal Repair System is intended for use in the arthroscopic fixation of longitudinal vertical meniscus lesions (bucket-handle lesions) located in the vascularized area of the meniscus (red-red and red-white zones).

Safety and Performance:
The following safety and performance data has been provided to support subtantial equivalence of the Mitek RapidLoc™ Meniscal Repair System:

Performance Testing:
- Strength comparison (RapidLoc™ Meniscal Repair System vs. Mitek "H" Fix)
- In vitro testing (RapidLoc™ Meniscal Repair System vs. PDS Suture)

Conclusion:
Based on 1) safety and performance data, and 2) similarities in design, operating principle, biocompatibility and sterilization method, the Mitek RapidLoc™ Meniscal Repair System has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Christine Kuntz-Nassif
Senior Regulatory Affairs Associate
Mitek Products
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K002406
Trade Name: Rapidloc™ Meniscal Repair System
Regulatory Class: II
Product Code: MAI, GAS and GAM
Dated: November 16, 2000
Received: November 17, 2000

Dear Ms. Kuntz-Nassif:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002406

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for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K002406